

510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

- | | | | |
|--------|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 1. (a) | Submitter Address: | George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medic sense.com | APR 17 2009 |
| 1. (b) | Manufacturer Address: | T.A.G. Medical Products D. N. Ashrat Kibbutz Gaaton 25130, Israel | |
| | Mfg. Phone: | Tel.: 972-3-647-4840 | |
| | Contact Person: | Dan Moor | |
| | Date: | April 16, 2009 | |
| 2. | Device & Classification Name: | Bone Fixation Screw, class II device (product code HWC). Latarjet Cortical Screw Set | |
| 3. | Predicate Device: | Depuy Cannulated Bone Screw K903811 Synthes 3mm Cannulated Bone Screw System K892823 | |
| 4. | Description: | The Latarjet Cortical Screw Set consists of an implantable fixation screw which is used for fixation of bone grafts or bone fragments to cortical bone in shoulder surgeries. The fixation screws are offered in the following overall lengths: <u>36mm – 42mm</u> . (features- other than the overall length- are identical on all). The set also includes a threaded bushing which attaches to the proximal end of the fixation screw. Its purpose is to position the screw firmly and safely during the fixation procedure. The bushing is provided in one size. The fixation screw and bushing are supplied in either in Titanium alloy or Stainless Steel. The Latarjet Cortical Screw Set is supplied non-sterile, for single patient use. | |
| 5. | Intended Use: | The Latarjet Cortical Screw Set is intended to provide the orthopedic surgeon a means of bone fixation and to assist in the management of fractures and reconstructive surgeries. | |
| 6. | Comparison of Technological Characteristics: | With respect to its indication for use, the Latarjet Cortical Screw Set is substantially equivalent to its predicate device in that it intended for the same clinical purpose. With respect to technology, the design is similar as confirmed by comparison, and the performance is the same as verified by validation. Based upon this, T.A.G. Medical Products believes that its device is safe and effective because it performs the same function in the same manner. | |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

T.A.G. Medical Products
% MedicSense, USA
Mr. George J. Hattub
291 Hillside Avenue
Somerset, Massachusetts 02726

APR 17 2009

Re: K083096

Trade/Device Name: Latarjet Cortical Screw Set
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 5, 2009
Received: March 9, 2009

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

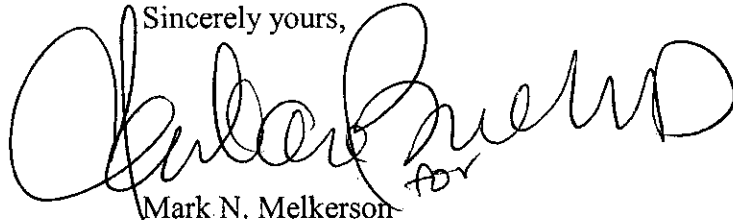
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a small "for" written below it.

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083096

Indications for Use

510(k) Number (if known):

Device Name: Latarjet Cortical Screw Set

Indications For Use: The Latarjet Cortical Screw Set is intended to provide the orthopedic surgeon a means of bone fixation and to assist in the management of fractures and reconstructive surgeries.

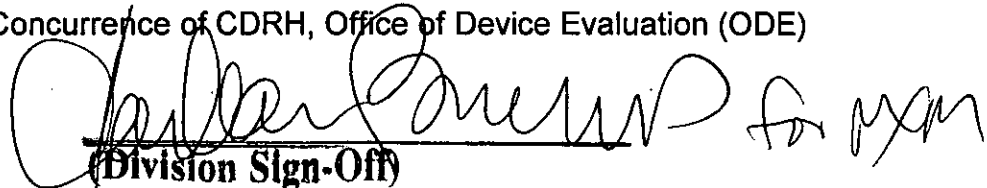
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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